REMARKS

Brief Description of the Amendments

Claims 27, 31, and 32 are currently amended. Claims 33-37 are new. Claims 1, 2, 4-7, and 25-37 are pending after entry of this amendment. No new matter has been introduced, as the currently amended and new claims are supported throughout the originally-filed specification (see, for example, paragraphs 24-27 and 34 of Publication No. 2004/0060508).

Reconsideration is respectfully requested.

Claim Rejections Under 35 U.S.C. § 103

I. Rejections of claims 1, 2, 4-7, 25, and 26 over Jendersee, Helfrich, and Scanlon

Claims 1, 2, 4-7, 25, and 26 were rejected under 35 U.S.C. §103(a) as being unpatentable over Jendersee et al. (US 5,836,965) (hereinafter "Jendersee") in view of Helfrich (US 5,308,338) and Scanlon et al. (US 2,845,346) (hereinafter "Scanlon"). Applicant respectfully traverses.

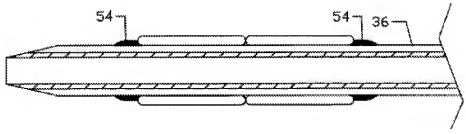
Claim 1

The examiner admits that Jendersee is "silent concerning the retaining member(s) having a porosity to the extent of a closed pore system" but that Helfrich teaches "catheters having cuffs made from porous material" and Scanlon teaches "that sintered metal while porous, can be made to have a closed pore system." The examiner concludes that, in view of the teachings of Helfrich and Scanlon it would have been "obvious to make the retaining member(s) of any appropriate porous and/or non-porous implantable material so as to retain the stent on the catheter." This analysis fails to establish a prima facie case of obviousness as explained below.

Claim 1 requires a "first member including a plurality of pores disposed on a stent support surface of the first member." The examiner equates retainers 54 of Jendersee (FIG. 7) with the "first member" of claim 1 and asserts that it would be obvious to make the retainers 54 out of "any appropriate porous and/or non-porous implantable material so as to retain the stent on the catheter." However, there is no indication in Helfrich that the porous cuffs 7, 8 (FIG. 1), 32, 33 (FIG. 6) would be appropriate for retaining a stent on Jendersee's stent delivery catheter. Unlike the Jendersee catheter, the Helfrich catheter does not carry a stent. The Helfrich catheter is implanted for a prolonged time period in a dialysis patient to facilitate drainage of bodily fluids that accumulate over time. The porous cuffs of the Helfrich catheter function to engage a patient's abdominal wall (col. 4:15-20) so as to keep the catheter in place and prevent "pistoning" (col. 1:43-45). It goes without saying that a stent is very different from a patient's abdominal wall, so it is **not predictable** that the porous material of Helfrich is appropriate for retaining the Jendersee stent.

Rather than having predictable results, evidence actually indicates that the porous material of Helfrich is inappropriate for retaining the Jendersee stent. In Jendersee, it is important for retainers 50, 52, 54 to "create a smooth transition between the balloon/stent area of the delivery device" (col. 7:36-39; and see FIG. 7 reproduced below) to facilitate moving the Jendersee's stent delivery catheter through the tight and tortuous confines of a patient's body lumen (col. 3:2-7).

FIGURE 7



However, the porous cuff material in Helfrich is illustrated as being very rough (see 32, 33 in FIG. 6 reproduced below), so a person reading Helfrich would not think of using the rough cuffs to create a smooth transition in the Jendersee device (FIG. 7 reproduced above).

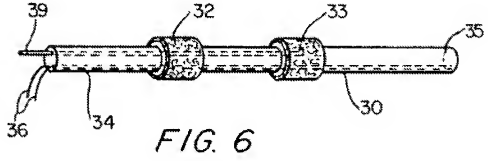


FIG. 6

Also, Helfrich indicates that the porosity of the cuffs permits ingrowth of tissue (col. 4:34-36), which is undesirable in stent delivery catheters. Ingrowth of tissue would hinder or eliminate the ability of stent delivery catheters to slide easily in and out of tight and tortuous bodily lumens. Thus, the cited references provide **no teaching, suggestion, or motivation** to make the retainer 54 of Jendersee out of a porous material and, in fact, specifically **teach away from the combination**. Moreover, the examiner's suggested modification of the Jendersee device is **contrary to what any person of ordinary skill in the art would do**.

In Jendersee, making the retainers 54 porous would serve no particular purpose related to retention of the stent, which is depicted in FIG. 7 above as two segments above balloon 36 and between retainers 54. The Jendersee stent is retained primarily by portions of the balloon which "expand part way around the stent and adhere thereto" (col. 3:28-31; see also FIG. 6 of Jendersee). This method of retention is referred to as "encapsulation" throughout Jendersee. The Jendersee retainers 50, 52, 54 are secondary to encapsulation, serving only to "further secure stent segment 10 to the balloon 36" (col. 7:36-40). As can be seen in FIG. 7 reproduced above, the Jendersee retainers 54 appear to block side to side movement of the stent by providing a force against opposite ends of the stent. Making the Jendersee retainers porous would not help provide a force against the ends of the stent, or otherwise help retain the stent.

Furthermore, the examiner does not articulate any reasoning with some rational underpinning as to why a porous material would be appropriate for the retainers 54 of Jendersee. The examiner merely states that it would be obvious to use "any appropriate porous and/or non-porous implantable material from which to make the retaining member(s), since it has been held to be within the general skill of the worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice." **Without support from the cited references, predictability, or articulated reasoning, the examiner's conclusion that a porous material is suitable for Jendersee's retainers 54 is insufficient as a mater of law**. See KSR v. Teleflex, 127 S.Ct. 1727, 1740-41, 82 USPQ2d 1385, 1396 (2007) ("[R]ejections on obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of

obviousness.") (quoting In re Kahn, 441 F.3d 997, 998, 78 USPQ2d 1329, 1336 (Fed. Cir, 2006)); see also MPEP 2141, III.

Scanlon does not cure the deficiency of Jendersee and Helfrich. Accordingly, Applicant respectfully submits that claim 1 is patentably allowable over Jendersee, Helfrich, and Scanlon.

Claims 2, 4-7, 25 and 26

Claims 2, 4-7, 25 and 26 depend from claim 1 and, thereby, include every feature of claim 1. As indicated above, claim 1 is patentably allowable over Jendersee, Helfrich, and Scanlon, so claims 2, 4-7, 25 and 26 are patentably allowable over Jendersee, Helfrich, and Scanlon for at least the same reason as claim 1.

II. Rejection of claims 27-32 over Jendersee and Helfrich

Claims 27-32 were rejected under 35 U.S.C. §103(a) as being unpatentable over Jendersee in view of Helfrich.

Independent claims 27, 31 and 32

The examiner admits that Jendersee is "silent concerning the cuff(s) or retaining member(s) having a porous layer thereon capable of absorbing or at least partially absorbing a fluid" but that Helfrich teaches "a catheter with cuffs made from porous implantable materials (i.e., polymers to sintered metal and ceramics) to promote the ingrowth of tissue." The examiner concludes that it would have been obvious "to make the cuff(s) or retaining member(s) of a porous layer of material as taught by Helfrich in the device of Jendersee et al in order to enable the absorption or retention of fluid when the stent is pretreated or enable tissue growth when the device is implanted." However, tissue growth is undesirable for the Jendersee device, as previously explained. Also, Jendersee does not indicate that absorption or retention of fluid is

desirable for the Jendersee stent delivery catheter, and the examiner has given **no rational underpinning** for making the Jendersee stent delivery catheter absorb or retain fluid.

In the Helfrich catheter, the absorption of fluid through the porous cuffs allows the cuffs to be permeated with and disinfected by liquid disinfectant introduced from below the porous cuffs (col. 4:40-56). Such a disinfection method is important for a drainage catheter that remains implanted in a person over a long period, even when the person is walking or performing other activities (col. 1:42). But the Helfrich disinfection method is unnecessary for stent delivery catheters, such as the Jendersee device, which are typically used for a relatively short time period and only in a sterile surgical environment. Accordingly, **there appears to be no reason at all for implementing Helfrich's disinfection method, or otherwise using a porous material, in the Jendersee device as suggested by the examiner**.

Apart from the features involving absorbency, the cited references also fail to make obvious the following features of independent claims 27, 31 and 32: "first and second elements capable of being moved closer or further from each other." The examiner asserts that this feature is met by Jendersee because "the retaining members and cuffs are placed on a workholder or catheter and moved together or further apart until the desired location of the retaining member or cuffs are affixed or attached..." The examiner appears to assert that the components for the Jendersee retainers are manually moved relative to each other when manufacturing the Jendersee device. However, Jendersee merely states that during manufacturing "retainers 54 may be attached over the balloon 36 prior to encapsulation, as shown in FIG. 7, or retainers 54 may be placed within the balloon 36, as shown in FIG. 8." Thus, there is no support in Jendersee for relative movement of the retainers 54 during the manufacturing process.

To expedite prosecution claims 27, 31, and 32 have been amended to recite: "the first and second elements capable of being moved ~~closer or further from~~ relative to each other to secure and release a stent." Thus, even if the examiner insists that Jendersee's retainers 54 are moved relative to each other during manufacturing, Applicant points out that the retainers 54 are incapable of moving relative to each other to release a stent. In use, after the retainers 54 are attached to the balloon 36, the fully manufactured Jendersee device is guided through a patient's vasculature to a lesion where the balloon 36 (see FIG. 7 reproduced above) under the stent is inflated, thereby expanding the stent into engagement with the lesion. The balloon is then deflated but the stent remains expanded, thus allowing the balloon and retainers to be pulled out from under the stent and out of the patient. Nowhere in Jendersee's stent releasing process are the retainers 54 moved relative to each other. Also, making the retainers 54 movable relative to each other to release the stent presents a danger to the patient because the retainers 54 might slip off the balloon and get lost in the patient's vasculature.

Accordingly, Applicant respectfully submits that claims 27, 31, and 32 are patentably allowable over Jendersee in view of Helfrich.

Claims 28-30

Claims 28-30 depend from claim 27 and, thereby, include every feature of claim 27. As indicated above, claim 27 is patentably allowable over Jendersee and Helfrich, so claims 28-30 are patentably allowable over Jendersee and Helfrich for at least the same reason as claim 27.

Conclusion

In light of the foregoing remarks and amendments, this application is considered to be in condition for allowance, and early passage of this case to issue is respectfully requested.

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Respectfully submitted,

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